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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,657	11/28/2000	Mark Christopher Doyle	257/087	7712

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ORRICK, HERRINGTON & SUTCLIFFE, LLP
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/03/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,657

Applicant(s)

DOYLE, MARK CHRISTOPHER

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Righi et al., 5,562,624. Righi et al. discloses a method comprising the steps of: inserting the needle into a patient's skin while holding the shield (12, 16 and 23) a predetermined distance therefrom; applying a distal force on a plunger (7) communicating with the cartridge to inject medication into the patient until the plunger contacts a latch member (16) extending from the passive needle guard; depressing the plunger (7) further to deflect the latch member to disengage the cooperating catches (17 and proximal end of 1), see column 3, lines 43-44, wherein the body becomes biased to move towards the retracted position; and releasing the distal force on the plunger, thereby retracting the body towards the retracted position, wherein the needle is substantially covered by the shield, see column 6, lines 14-27.

As to claim 2, the needle is withdrawn from the patient, as the body is retracted towards the retracted position, see column 6, lines 42-46.

As to claim 3, the needle is withdrawn into the shield as the body is retracted towards the retracted position, see column 6, lines 42-50.

As to claim 4, the cooperating detents (23 and 203; or alternatively, 25 and 303) on the shield and body engage one another when the body is retracted to the retracted position, thereby preventing subsequent proximal movement of the shield, see column 6, lines 50-62.

As to claim 5, the latch member (16) comprises an elongate finger extending proximally from the shield towards the plunger, the finger being compressed and thereby deflected radially outward to disengage a catch (17) thereon from a mating catch (proximal end of 1) on the body when the plunger is depressed, see Figure 2.

As to claim 6, the plunger includes a radial portion (9) for engaging a proximal tip of the finger as the plunger is depressed, the finger being compressed by the radial portion as the plunger is depressed to deflect the finger radially outward to disengage the catch thereon from the mating catch on the body.

As to claim 7, the distal force is applied to the plunger (9 and 7) while holding finger grips (13) on the shield, thereby holding the shield the predetermined distance from the patient's skin.

As to claim 8, the shield remains substantially stationary with respect to the patient's skin while medication is injected into the patient, see column 6, lines 23-27.

As to claim 9, the shield does not come in contact with the patient's skin while medication is injected into the patient, see column 6, lines 23-27, and lines 42-47.

As to claim 10, a medicine cartridge (7) is provided in the body.

As to claim 11, cooperating detents (23 and 203; or alternatively, 25 and 303) on the shield and body engage one another when the needle is substantially contained

within the shield, thereby preventing subsequent movement of the body with respect to the shield.

As to claim 12, the latch member (16) comprises an elongate finger extending proximally from the shield towards the plunger, the finger being compressed and thereby deflected radially outward to disengage a catch thereon from a mating catch on the body when the plunger is depressed.

As to claim 13, the plunger includes a radial portion (9) for engaging a proximal tip of the finger plunger as the plunger is depressed, the finger being compressed by the radial portion as the plunger is depressed to deflect the finger radially outward to disengage the catch thereon from the mating catch on the body.

As to claim 14, Righi et al discloses a body (1 and 3) having proximal and distal ends and a cavity therein for receiving a medicine cartridge having a distal tip for administering a medication from within the cartridge; a shield (12, 16 and 23) having proximal and distal ends, the shield being slidably attached to the body, the body being biased to retract with respect to the shield from a first position wherein the distal tip of the cartridge is exposed towards a second retracted position for withdrawing the distal tip of the cartridge into the shield, see column 6, lines 47-50; cooperating catches (i.e., 17 on shield, and proximal end of body 1 in Figure 2) on the body and shield for holding the body and shield in the extended position; and a latch member (16) extending proximally from the proximal end of one of the shield and the body, the latch member being deflectable for disengaging the cooperating catches upon depression of a

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plunger, see column 6, lines 14-27, coupled to the medicine cartridge, whereby the shield may be automatically advanced to the extended position.

As to claim 15, a trigger flange (19) extends radially outward from the plunger, the trigger flange configured for deflecting the latch member to disengage the cooperating catches upon depression of the plunger.

As to claim 16, the trigger flange (19) comprises a pocket for receiving a proximal tip of the latch member, whereby an intermediate portion of the latch member (16) is deflected radially outward for disengaging the cooperating catches when the tip of the latch member is received in the pocket and the plunger is depressed distally.

As to claim 17, the trigger flange (19) is located at a predetermined position location on the plunger for disengaging the cooperating catches at an intermediate portion of the plunger stroke.

As to claim 18, the latch member (16) comprises a proximal tip surface (18) that is angled radially outward, whereby, upon depression of the plunger, the trigger flange (19) engages the surface to deflect the latch member radially outward to disengage the cooperating catches.

As to claim 19, the trigger flange (19) comprises a tapered distal edge, see Figure 2 whereby, upon depression of the plunger, the tapered distal edge of the trigger flange engages the latch member (17 and 16) to deflect the latch member radially outward to disengage the cooperating catches.

As to claim 20, one or more finger grips (26) extend from the shield (12).

As to claim 21, the body and shield comprises cooperating detents (proximal end of 23 and 203) for substantially permanently maintaining the body in the retracted position.

As to claim 22, a medical cartridge (7 and 4) is received in the cavity such that a distal tip of the cartridge extends beyond the distal end of the body.

As to claim 23, the distal tip of the cartridge comprises a needle (4).

As to claim 24, a locking mechanism (10) is provided on the proximal end of the body for locking the cartridge received within the cavity.

Response to Arguments

Applicant's arguments filed August 27, 2002 have been fully considered but they are not persuasive. Applicant argues that, as to claim 10, Righi et al does not disclose a body having a medicine cartridge therein, see page 3, lines 13-14. In response, Examiner asserts that the medicine cartridge is not defined structurally in the claims, and thus claim 10 does not distinguish over Righi et al. Furthermore, Righi et al. discloses the shield as claimed, see column 6, lines 14-27.

Moreover, as to claim 14, Examiner referred to column 6, lines 47-50, where Righi discloses the needle in a retracted position as claimed, the cartridge comprising needle (4), just like Applicant's cartridge in claim 14, or claim 23.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

A.L. 
December 1, 2002


ANH TUAN T. NGUYEN
PRIMARY EXAMINER
